

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

[53 FR 15980, May 4, 1988, as amended at 72 FR 61028, Oct. 26, 2007; 73 FR 75595, Dec. 12, 2008]

**§ 152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.**

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including,

at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

**§ 152.114 Approval of registration under FIFRA sec. 3(c)(7)—Products that contain a new active ingredient.**

An application for registration of a pesticide containing an active ingredient not in any currently registered product may be conditionally approved for a period of time sufficient for the generation and submission of certain of the data necessary for a finding of registrability under FIFRA sec. 3(c)(5) if the Agency determines that: